

Appl. No. : 09/447,227
Filed : November 22, 1999

REMARKS

Claims 33, 34, 38, 41, 42, 48, 49, and 54-83 are pending in this application. Claims 34, 38, 41, 42, 48, 54, 62, 63, and 76-83 have been amended. Support for the amendments is found in the specification and claims as filed (see, for example, page 13, lines 17-23).

Claim Rejection - 35 U.S.C. §103(a) - Khan in view of Picha

Claims 33, 34, 38, 41, 42, and 56-64, 66-78, and 80-83 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,387,327 to Khan et al. ("Khan") in view of U.S. Pat. No. 5,271,736 to Picha ("Picha"). To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter alia*, the step of "providing an implantable device comprising ... a housing comprising a convexly protruding sensing mechanism... and an angiogenic layer positioned over said convexly protruding sensing mechanism..." Claim 38 recites a method of monitoring glucose levels, comprising, *inter alia*, the step of "providing ... a device comprising a housing and a sensor ... wherein said housing comprises a protruding convexly curved portion over which a sensing membrane and a vascularization promotion layer are located, and wherein the sensor is directly in contact with the protruding convexly curved portion..."

Khan a detector including disclose a sleeve 12 including a measurement electrode 11 located therein, intended for a measurement of glucose in blood flow (e.g., a vein). The measurement electrode 11 of Khan is positioned within a sleeve 12 with a membrane 15 located over one end 14. As described in col. 5, lines 56 – 64 of Khan, the implantable unit is intended

for implantation in a vein of a patient, and a pump is employed to pump the fluid in and out of the sleeve 22 (see col. 4, lines 16-18).

Picha teaches covering the outside of an implantable sensor device with foam (col. 5, lines 43-48) for implantation in the soft tissue to minimize the formation of a fibrous capsule and enhance the fixation of the implant and increase vascular ingrowth (see col. 5, lines 59-64). Examiner asserted in the office action that it would have been obvious to modify Khan to use the layer of Picha, to improve the measurement process. However, Applicants assert that one of ordinary skill in the art would not have been motivated to modify Khan with the foam of Picha. If one were to apply the foam of Picha to Khan, the detector of Khan would be unsuitable for its intended use; namely, for use within a vein of a host. Firstly, vascularization is unlikely to occur and is undesirable in a vein; secondly, the structure of the foam that promotes vascularization would likely cause clotting and/or otherwise cause blockage of the blood flow through the sleeve 12 of Khan, and would not improve the measurement process. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a) – Wilson et al in view of Picha

Claims 33, 34, 38, 41, 42, 48, 49 and 54-83 have been rejected under 35 U.S.C. §103(a) as obvious over Wilson et al. in view of Picha. To establish a *prima facie* case of obviousness, the prior art references must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143. Evidence of unobvious or unexpected advantageous properties can rebut *prima facie* obviousness. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Superiority of a property shared with the prior art is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a).

Claim 34 recites a method of measuring glucose in a biological fluid comprising, *inter alia*, the step of “providing an implantable device comprising ... a housing comprising a convexly protruding sensing mechanism... and an angiogenic layer positioned over said convexly protruding sensing mechanism... .” Claim 38 recites a method of monitoring glucose levels, comprising, *inter alia*, the step of “providing ... a device comprising a housing and a sensor ... wherein said housing comprises a protruding convexly curved portion over which a sensing

membrane and a vascularization promotion layer are located, and wherein the sensor is directly in contact with the protruding convexly curved portion..."

Wilson discloses a device including an electrode 12, exposed by a cavity 16 in the insulator 14, over which an enzymatic indicating layer 21 is formed. The sensing mechanism 12 of Wilson is neither a convexly protruding sensing mechanism nor is the "sensor directly in contact with a protruding convexly curved portion." Picha teaches covering the outside of an implantable sensor device with foam (col. 5, lines 43-48) for implantation in the soft tissue to minimize the formation of a fibrous capsule and enhance the fixation of the implant and increase vascular ingrowth (see col. 5, lines 59-64). If one were to apply the foam of Picha to the device 25 of Wilson et al., it would neither assist in the formation of vasculature adjacent to a convexly protruding sensing mechanism nor place the sensor directly in contact with a protruding convexly curved portion, as claimed.

Applicants note that a protruding region that is convexly curved or has a curvature offers advantages over the configurations of the prior art, namely, superior performance in the formation of vasculature in the sensor interface region. The overall curvature of the surface on which the sensing region is located, including rounded edges, invokes a generally uniform foreign body capsule around that surface, decreasing inflammatory response and increasing analyte transport at the device-tissue interface. The curvature ensures that the sensing region is resting against the tissue and that when tissue contraction occurs, forces are generated downward on the sensing region so that the tissue attachment is maintained. The downward forces bring the tissue into contact with porous biointerface materials used for ingrowth-mediated attachment and for biointerface optimization. Accordingly, the curvature of the sensing region, not just its protrusion, is important to the process of vascularization.

Because neither Wilson nor Picha, alone or in combination, disclose a convexly protruding sensing mechanism or a sensor directly in contact with a protruding convexly curved portion and including an angiogenic layer (or vascularization promotion layer) as claimed, and because Applicants' a convexly protruding sensing mechanism, or sensor directly in contact with a protruding convexly curved portion, including an angiogenic layer (or vascularization promotion layer) as claimed, is responsible for superior vascularization when compared to prior art configurations, Applicants respectfully request withdrawal of the rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/27/2001
10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	1/29/2004
11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	12/22/2004
08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	3/4/1997
09/447227	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/22/1999
11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2004
10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	5/22/2002
11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005

11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	8/22/2003
11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/22/2003
10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/10/2004
11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	1/17/2007
10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	7/21/2004
10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/21/2004
11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
11/675063	ANALYTE SENSOR	2/14/2007
11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	7/21/2004
10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	7/21/2004
10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/18/2005
10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003

11/865660	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	10/1/2007
10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/22/2003
11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/2/2006
11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	6/14/2007
11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	12/8/2004
10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	11/16/2004
11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	12/7/2004
10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	11/17/2004
11/055779	BIOINTERFACE WITH MACRO-AND MICRO-ARCHITECTURE	2/9/2005
10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	2/26/2004
11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	12/3/2004
11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	1/11/2005
11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	1/11/2005
10/838912	IMPLANTABLE ANALYTE SENSOR	5/3/2004
10/838909	IMPLANTABLE ANALYTE SENSOR	5/3/2004
10/838658	IMPLANTABLE ANALYTE SENSOR	5/3/2004
10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	7/6/2004
11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	3/10/2005

11/077715	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077883	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077739	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077740	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077765	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/078230	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/078232	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077713	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077693	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077714	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/925603	TRANSCUTANEOUS ANALYTE SENSOR	10/26/2007
11/077643	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/078072	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/360262	ANALYTE SENSOR	2/22/2006
11/411656	ANALYTE SENSOR	4/26/2006
11/360299	ANALYTE SENSOR	2/22/2006
11/439630	ANALYTE SENSOR	5/23/2006
11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/9/2006
11/404929	ANALYTE SENSING BIOINTERFACE	4/14/2006
11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/18/2006
11/654140	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
11/157746	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
11/157365	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
11/158227	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
11/334876	TRANSCUTANEOUS ANALYTE SENSOR	1/18/2006
11/360252	ANALYTE SENSOR	2/22/2006
11/360819	ANALYTE SENSOR	2/22/2006
11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	1/17/2006
11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006

11/360250	ANALYTE SENSOR	2/22/2006
11/842151	ANALYTE SENSOR	8/21/2007
11/543396	ANALYTE SENSOR	10/4/2006
11/543490	ANALYTE SENSOR	10/4/2006
11/543404	ANALYTE SENSOR	10/4/2006
11/691426	ANALYTE SENSOR	3/26/2007
11/691432	ANALYTE SENSOR	3/26/2007
11/691424	ANALYTE SENSOR	3/26/2007
11/691466	ANALYTE SENSOR	3/26/2007
11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	5/18/2007
11/855101	TRANSCUTANEOUS ANALYTE SENSOR	9/13/2007
11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/13/2007
11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/27/2007
11/865572	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/1/2007
11/681145	ANALYTE SENSOR	3/1/2007
11/503367	ANALYTE SENSOR	8/10/2006
11/690752	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2007
11/734184	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
11/734203	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
11/734178	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
11/445792	ANALYTE SENSOR	6/1/2006
11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	10/10/2006
10/846150	ANALYTE MEASURING DEVICE	5/14/2004
09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/21/2000
10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	9/9/2003
09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	8/11/2000

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09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	7/27/2001
11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/19/2005
07/216683	BIOLOGICAL FLUID MEASURING DEVICE	7/7/1988

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated:

3/21/08

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